UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
at BECKLEY

UNITED STATES,	)	
STATE OF CALIFORNIA,	)	
STATE OF GEORGIA,	)	
STATE OF ILLINOIS,	)	
STATE OF NEW YORK	)	
STATE OF TENNESSEE	)	
EX REL.	)	
	)	
STEVEN MAY and	)	
ANGELA RADCLIFFE,	)	
	)	
Plaintiffs,	)	
	)	**CIVIL ACTION NO. 5:10 -CV-01423_**
v.	)	
	)	
PURDUE PHARMA L.P.,	)	
a limited partnership,	)	
and	)	
PURDUE PHARMA, INC.,	)	
	)	
Defendants.	)	

AMENDED COMPLAINT

1. **Steven May** and **Angela Radcliffe**, bring this False Claims Act (the "FCA") action as relators in the name of the United States Government, and States of California, Georgia, Illinois, New York and Tennessee to recover damages for Defendants' violations of the FCA, and the respective comparable state statutes. The relators did not derive their allegations of the False Claims Act violations from public disclosures and, in any case, Steven May is an original source, as defined in section 3730(e)(4) of the FCA, and under the respective state statutes, of the information on which the allegations contained herein

are based, which information was disclosed to the Government and respective state governments prior to the filing of this action..

Parties

2. Steven May, relator, is an individual and citizen of the United States of America residing at 7013 Campbell Drive, Salem, Virginia. At various times described herein he was an employee of Defendant Purdue Pharma L.P.

3. Angela Radcliffe, relator, at all relevant times, was and remains the wife of Mark Radcliffe, who was an employee of Defendant Purdue Pharma, L.P.

4. Purdue Pharma L.P. is a limited partnership organized under the laws of the State of Delaware and at all times described herein was engaged in the business of developing and marketing prescription drugs and other products utilized in the health care industry.

5. Purdue Pharma, Inc., a Delaware corporation, is the general partner of Defendant Purdue Pharma, L.P.

6. Defendants are collectively and individually referred to herein as Defendant or Purdue, unless otherwise indicated.

Jurisdiction And Venue

7. This action arises under the False Claims Act, 31 U.S.C. § 3729 *et seq.* This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. §§ 3732(a) and (b), and 28 U.S.C. § 1331 in that this action arises under the laws of the United States.

8. Venue is proper in this Court pursuant to 28 U.S. C. §§ 1391(b), and 1391©, and under 31 U.S.C. § 3732(a) because at least one of the defendants transacts business within the district, and some of the acts proscribed by the False Claims Act occurred within the district.

Facts

9. From 1995 to the present, Purdue has been selling a controlled-release pain relief tablet called OxyContin, which has as its active ingredient, oxycodone.

10. During that period, to generate sales, Purdue engaged in a face-to-face marketing to physicians and other institutional decision makers who could buy or authorize the purchase of OxyContin.

11. Purdue determined that the cost of OxyContin was a key concern of those physicians and decision-makers. Therefore, Purdue trained its sales representatives to make certain specific representations about OxyContin and its cost to assuage those concerns and to induce those physicians to prescribe, and other decision makers to buy, OxyContin. Purdue's sales representatives then incorporated those representations into their face-to-face marketing of OxyContin to those physicians and other decision makers.

12. Those representations consisted of statements as to OxyContin's equianalgesic cost. The equianalgesic cost is the comparative cost of a pain medication when all factors are equalized to provide a typical patient with the same pain relief as competing pain medications. To do this, Purdue compared OxyContin's effective pain relief and cost per milligram to a benchmark — Purdue's drug MS Contin, which was a best-seller and had been on the market for several years and therefore was well-known in the medical community. Purdue represented that one milligram of OxyContin would give the same

pain relief as two milligrams of the benchmark, MS Contin. Purdue then represented that, despite OxyContin's higher per milligram cost, OxyContin was cheaper than MS Contin when they were measured based on the pain relief that they provided; thus, the equianalgesic cost of OxyContin was less. As is well known in the medical community, a pain reliever's effectiveness will vary from individual to individual and the dosage has to be titrated for each patient, thus, Purdue's representation purported to show the *average* equianalgesic cost of OxyContin rather than the cost for each patient, or even a specific patient.

13. Purdue's representations were false and misleading, and Purdue knew that they were false and misleading. Purdue knew that there was no scientific basis for making those claims and that the scientific evidence that existed indicated that the equianalgesic ratio of OxyContin and MS Contin was no greater than 1.5 to 1 - - substantially and materially less than the 2 to 1 ratio. To help gain credibility for its bogus 2:1 analgesic ratio claim, Purdue deviously had its sales representatives, in their face-to-face marketing, point to OxyContin's package insert that mentioned a 2:1 equianalgesic ratio of OxyContin and MS Contin. However, the ratio stated in the insert was derived from a study of a single dose of the respective drugs. While the active ingredients of MS Contin and OxyContin, morphine and oxycodone, respectively, may be administered appropriately as a single dose for the treatment of acute, short-term pain, when those ingredients are in controlled-released products like MS Contin and OxyContin, single dosing is not indicated. Rather, MS Contin and Oxycontin are indicated only for chronic pain, as was specified by Purdue's package inserts for these products. As a result of the labeled use of OxyContin for only chronic pain, Defendant knew that the only

equianalgesic ratio of morphine to oxycodone (the active ingredient in OxyContin) relevant to the indicated use of OxyContin was materially less than 2:1 and produced an equianalgesic ratio which clearly demonstrated MS Contin's superior cost-effectiveness.

14. At all relevant times, Purdue conducted its marketing of OxyContin through its national team of sales representatives. Purdue gave each of its new sales representatives three weeks of training at Purdue's corporate headquarters, located in Stamford, Connecticut.

15. Purdue included the false 2:1 equianalgesic ratio and cost savings assertions into that training program. For instance, Relator Radcliffe's husband, Mark Radcliffe, was hired by Defendant as a drug representative on or around January 23, 1996, and during his first week of training, Defendant's Training Department Manager Dennis Menlo, addressing the issue of the cost of OxyContin for the sales force training class, told the class that according to the equianalgesic 2:1 conversion factor of morphine to oxycodone, OxyContin is actually a little less expensive than MS Contin.

16. Defendant's sales reps then went out and used the 2.1 equianalgesic ratio and cost savings misrepresentations in its marketing to physicians and others.

17. The 2:1 equianalgesic ratio and false cost savings lies were key components of Purdue's marketing of OxyContin.

18. Mark Radcliffe began marketing OxyContin in 1996 using the fraudulent 2:1 lies he had been told to use by Purdue (without knowing they were lies). Later, he became the district manager and he and the sales reps under him employed those lies in their marketing of OxyContin. Those sales reps that Radcliffe managed included Brad White (Charleston, West Virginia), Patty Carnes (Huntington, West Virginia), Kim Keith (Tennessee), and Relator May.

19. Relator May was hired by Purdue in November 1999 as a sales rep and he also began marketing OxyContin with the 2:1 lies (without knowing they were lies).

20. Relator May, Radcliffe, and/or the sales reps under Radcliffe marketed OxyContin to physicians, pharmacies, and hospices throughout their sales territories. Some of the physicians to whom they successfully marketed OxyContin with the 2:1 ratio lies were physicians in Beckley, West Virginia (some of whom were John DiStefano, Carl Larson, Charles Porterfield, and Bruce Cannon), Princeton, West Virginia (some of whom were John Muldoon, David Hopper, Stanely Hamaker, and Marshall Long), Huntington, West Virginia (some of whom were Bruce Ratcliff, Charles McCormick, and David Patrick); Bluefield, Virginia (some of whom were Robert Miller, Walid Azzo, and Mary Kistner); Richlands, Virginia (some of whom were Howard Scott, James McVey and Ramon Motos), Pulaski, VA (some of whom were K. Pendergrast, and Linda Cheek), Pearisburg, VA (some of whom were R. Devereaux and Dr. McMahon), and Blacksburg, VA (Richard Wilson).

21. Specific false Medicaid claims resulting from Purdue's false marketing include the following. In their work for Purdue, Mark Radcliffe and Mark Ross, one of Purdue's sales reps, called upon Dr. Jarvis, who worked at the Rainelle Medical Center in Rainelle, West Virginia, in the early Summer of 1998. During the meeting, Ross made the false relative potency and cost savings claims noted above to a physician Dr. Phillip Jarvis. Those false claims induced Dr. Jarvis, and he admitted that they did, to prescribe OxyContin to some of his patients. A list of the Medicaid claims filed for some of those prescriptions, along with some key details of each of those claims including the type of OxyContin and the dollar amount of the claim, is attached hereto as Exhibit A and is

incorporated by reference in full into this complaint. The patient names and some of the patient identifying information on the list are redacted for privacy reasons. Dr. Jarvis would not have, and has acknowledged that he would not have, issued the listed prescriptions of OxyContin to his patients had he known that the cost savings and potency representations made by Ross were false. Those false representations were material to Dr. Jarvis' decision to prescribe OxyContin, and Medicaid's decision to pay for the prescriptions in that the misrepresentations had a natural tendency to influence those decisions.

22. At Purdue's direction, May, Mark Radcliffe and his subordinates also marketed OxyContin with the 2:1 lies to federal health care institutions, which made purchases based thereon. Those hospitals and clinics included;

a) **West Virginia** – Beckley Area Medical Clinic, the Rural Acres Clinic (Beckley)

The Rainelle Clinic; and the Veterans' Administration Medical Center ("VAMC") in Martinsburg

b) **Virginia –** the VAMCs in Salem and Richmond

c) **California** – the VAMCs in San Francisco, Fresno, and Palo Alto

23. For instance, Relator May, between October and December 2004, engaged in heightened marketing of OxyContin to the Medical Director, Chief Pharmacist Carlos Tam, pharmacy staff, staff physicians, and nurses of the Salem, Virginia VAMC using the fraudulent 2:1 ratio to convince them that OxyContin was cost-effective by showing that it was cheaper that MS Contin, and, as a result, the Salem, Virginia VAMC made purchases.

24. May left the employment of Purdue on January 1, 2005. He was not aware that the 2:1

marketing claims he had made were fraudulent until after he had left Purdue's employment.

25. Outside of May's sales district, Purdue was marketing and selling OxyContin to physicians, pharmacies, hospitals, and hospices with the 2:1 lies on a nationwide basis in the same way that May was marketing and selling OxyContin within his sales district. Some of the hospitals to which Purdue's sales reps marketed and sold OxyContin with the 2:1 lies were as follows:

California – Desert Hospital, San Diego Hospice, UCLA, and San Francisco General

Illinois – Cook County Hospital

Georgia – Medical Center of Central Georgia

Virginia – Medical College of Virginia

Purdue also marketed and sold its OxyContin with its 2:1 lies to US Prison, Indian Reservations, and other recipients whose purchases were being funded by federal dollars.

26. As a result of Purdue's fraudulent marketing efforts for OxyContin, sales of the drug skyrocketed.

27. Purdue was aware that a large portion of its OxyContin sales were paid, directly or indirectly, by the federal government, and that about a quarter of all OxyContin prescriptions being written by private physicians were being paid by Medicaid.

28. Purdue was aware that OxyContin did not provide double the pain relief of the benchmark drug, MS Contin, for its labeled use on a per milligram basis (in fact it was materially less), and, as a result did not provide the cost effectiveness that Purdue told the physicians and other decision makers that it did provide.

29. Purdue encouraged physicians to write prescriptions that were paid by Medicaid and other government programs for OxyContin that was materially less potent, on a per milligram basis, and, consequently, materially more expensive than the OxyContin that was described by Purdue in its marketing to those physicians.

30. Purdue knowingly made these false and fraudulent cost savings and potency representations to physicians and other decision makers that were material, and had a natural tendency to influence and/or were capable of influencing their decisions to prescribe OxyContin, and to purchase and pay for it.

COUNT I

Violations Of Section 3729 Of The Federal False Claims Act Arising Out Of Defendant's False Marketing Claims Of The Per Milligram Potency And Relative Cost Of OxyContin

31. Relator repeats and re-alleges each and every allegation contained in all of the allegations set forth above.

32. Purdue's actions above constituted violations of subsection 3729(a) of the False Claims Act.

33. In making its misrepresentations, Purdue intentionally and fraudulently (or at least with a reckless disregard for the truth) lied to physicians and other decision makers that each milligram of OxyContin provided a greater quantity of pain relief than it actually possessed for its only approved use. This false two-to-one misrepresentation also was the basis for Purdue's mispresentation that the cost of OxyContin per equianalgesic dose was materially less than it actually was. Accordingly, during the period when Purdue was marketing OxyContin with these false misrepresentations, the Government paid

for a drug that gave pain relief in an amount that was materially less, on a per milligram basis than represented and consequently, the Government incurred a materially greater cost for that pain relief, than Purdue represented that the Government would incur. Each OxyContin prescription paid for by Medicaid constituted a false or fraudulent claim to the Government when the pharmacy sought reimbursement from the Government because the Government was getting, on behalf of the Medicaid patient, materially less OxyContin, in terms of equianalgesic pain relief, than Purdue represented to the prescribing physician and others.

34. Purdue's two-to-one efficacy claim was misleading and fraudulent. And they were clearly material because they were representations involving key characteristics of OxyContin —its potency, and its cost. Physicians and other decision makers were deceived by Purdue into believing that, by prescribing or buying OxyContin, they were saving the payor of the drug, the Government, a lot of money. Purdue is liable, pursuant to 31 U.S.C. § 3729, for each of those false or fraudulent claims. As a result of Purdue's false statements, Medicaid and other government programs did not purchase the product for which they had agreed to buy, but rather a product that had materially less equianalgesic potency and cost effectiveness than Defendant had represented it possessed. Thus, in its purchases of OxyContin, as a result of Purdue's false and fraudulent statements, the government did not get the benefit of the bargain.

35. Relators are unable to identify at this time all of the false or fraudulent claims which were caused by Purdue's conduct. Purdue's misrepresentations, systematically made nationwide over a period of several years, generated a huge number of false and fraudulent claims spanning the years 1996 to 2009. Additionally, the false claims —

primarily prescriptions that were fraudulently induced by Purdue, were usually submitted to pharmacies with whom Relators had no dealings. Additionally, these records are usually protected by medical record confidentiality statutes and relators would generally have no access to them. Thus, the listing of all of the individual false claims in this complaint

is neither feasible, nor practical, and is not required.

36.` The running of the applicable statute of limitations for those claims that were also asserted in the earlier action filed by Mark Radclffe against Purdue in the Western District of Virginia was equitably tolled during the pendency of that earlier action, and in any case, the running of the statute of limitations for all of the claims alleged in this complaint was suspended by the operation of the Wartime Suspension of Limitations Act (WSLA), which operation was triggered at various relevant times, including September 18, 2001.

COUNT II

Violations Of The California False Claims Act

37. Relator repeats and re-alleges each and every allegation contained in all of the

allegations set forth above.

38. Medicaid is a program jointly funded by the federal and all fifty state governments, including the State of California.

39. Purdue, through its national sales force, marketed and sold OxyContin in all fifty states with its 2:1 lies, including California. Consequently, the resulting prescriptions that were paid by Medicaid in California were paid in part by the State of California.

40. Purdue's actions above constituted violations of section 12651(a) of the California False Claims Act, Cal. Code §§ 12650-656, for those false and/or fraudulent claims that were submitted to, and/or paid by California Medicaid, or that were otherwise paid, or submitted for payment to the State of California.

COUNT III

Violations of New York False Claims Act

41. Relator repeats and re-alleges each and every allegation contained in all of the allegations set forth above.

42. Purdue's actions above constituted violations of section 189 of the New York False Claims Act, N.Y Code Art. XIII, for those false and/or fraudulent claims that were submitted to, and/or paid by New York Medicaid, or that were otherwise paid, or submitted for payment to the State of New York.

COUNT IV

Violations of Georgia State False Medicaid Claims Act

43. Relator repeats and re-alleges each and every allegation contained in all of the allegations set forth above.

44. Purdue's actions above constituted violations of section 49-4-168.1 of the Georgia State False Medicaid Claims Act, for those false and/or fraudulent claims that were submitted to, and/or paid by Georgia Medicaid.

COUNT IV

Violations of Illinois False Claims Act

45. Relator repeats and re-alleges each and every allegation contained in all of the allegations set forth above.

46. Purdue's actions above constituted violations of subsection 3(a) of the Illinois False Claims Act, for those false and/or fraudulent claims that were submitted to, and/or paid by Illinois Medicaid, or that were otherwise paid, or submitted for payment to the State of Illinois.

COUNT V

Violations of the Tennessee Medicaid False Claims Act

47. Relator repeats and re-alleges each and every allegation contained in all of the allegations set forth above.

48. Purdue's actions above constituted violations of section 71-5-182(a) of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181*et seq.*, for those false and/or fraudulent claims that were submitted to, and/or paid by Tennessee Medicaid.

WHEREFORE, the Relators May and Radcliffe demand judgment on behalf of the

United States, California, New York, California, Georgia, Illinois, and Tennessee, together with all penalties, costs, fees, awards, and interest to the fullest extent permitted by 31 U.S.C. § 3730, and the respective state statutes, as a result of Purdue's actions.

RELATORS DEMAND A TRIAL BY JURY ON ALL CLAIMS.

Respectfully submitted,

STEVEN MAY

ANGELA RADCLIFFE

By: /s/ Paul Roop

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